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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,943	06/25/2001	William A. Mittelstadt	56842USA4A.002	9282

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EXAMINER

PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3772

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/888,943	Applicant(s) MITTELSTADT ET AL.	
	Examiner Nihir Patel	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11.09.2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on November 9th, 2006, with respect to claims 15-48 have been fully considered and are persuasive. The previous rejection(s) of the office action dating August 9th, 2006 has been withdrawn. However, the double patenting rejection from the previous office action still stands.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **15, 17-32, 34-42 and 44-50** are rejected under 35 U.S.C. 102(b) as being anticipated by Lübeck (1213249).

4. **As to claim 1**, Lübeck discloses an apparatus that comprises a facemask having at least one opening for receiving a unidirectional valve (**see page 2 4th paragraph**); and a unidirectional valve comprising valve body (**see figure 1**) including a frame **10** (**see figure 1**), a valve opening through the frame (**see figures 1 and 3**), and a valve seat **11** extending from the frame and at least partially surrounding the valve opening (**see figures 1 and 3**), and a valve flap **1** (**see figure 1**) having a first portion attached to the frame and an adjacent second portion free to move from the first portion when the second portion is in contact with at least a part of the valve seat to a second position where at least part of the second portion is spaced from the valve seat (**see figures 1 and 3**), wherein the valve flap has a contour shape, and further wherein at

least a portion of the contour shape of the valve flap is at least partially flattened when the valve flap contacts the valve seat (see **figure 1**); wherein the valve flap further comprises a top surface and a bottom surface , and at least one support element **2** extending from the top surface of the valve flap (see **figure 1**), wherein the at least one support element provides the contour shape of the valve flap (see **figures 1 and 2**).

5. As to **claim 17**, Lübeck discloses an apparatus wherein the unidirectional valve is an exhalation valve (see **page 2 3rd paragraph**).

6. As to **claim 18**, Lübeck discloses an apparatus wherein the unidirectional valve is an inhalation valve (see **page 2 3rd paragraph**).

7. As to **claim 19**, Lübeck discloses an apparatus wherein the valve flap comprises a plurality of support elements **4, 5 and 6** (see **figure 5**), wherein each of the plurality of support elements is spaced from each adjacent support element (see **figure 5**).

8. As to **claim 20**, Lübeck discloses an apparatus wherein the valve flap further comprises a first side spaced from a second side, and wherein the valve contour varies between the first and second sides (see **last paragraph on page 1**).

9. As to **claim 21**, Lübeck discloses an apparatus wherein the valve flap has a compound curvature (see **last paragraph on page 1**).

10. As to **claim 22**, Lübeck discloses an apparatus wherein the valve flap further comprises a first end spaced from the second end, and wherein the valve contour varies between the first and second ends (see **last paragraph on page 1**).

11. As to **claim 23**, Lübeck discloses an apparatus wherein the valve seat is generally planar and the valve flap has a curvature that causes a bias of the valve flap toward the valve seat to provide a seal between the valve flap and the valve seat (**see figure 1**).

12. As to **claim 24**, Lübeck discloses an apparatus wherein at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap contacts the valve seat (**see figure 1**).

13. As to **claim 25**, Lübeck discloses an apparatus wherein the bias of the valve flap toward the valve seat is sufficient to provide a seal between the valve flap and the valve seat in any orientation of the unidirectional valve (**see figure 1**).

14. As to **claim 26**, Lübeck discloses an apparatus wherein the frame of the valve body includes an angled portion adjacent the valve seat (**see figure 3**).

15. As to **claim 27**, Lübeck discloses an apparatus wherein the valve flap is removably attached to the valve body (**see page 3 paragraph 2**).

16. As to **claim 28**, Lübeck discloses an apparatus that comprises a facemask having at least one opening for receiving a unidirectional valve (**see page 2 4th paragraph**); and a unidirectional valve comprising valve body (**see figure 1**) comprising a valve opening; and a valve flap 1 (**see figure 1**) having a first portion attached to the frame and an adjacent second portion that seals the valve opening (**see figure 1**), wherein the valve flap has curvature from the first end spaced from the second end when the valve flap is not attached (**see last paragraph on page 1**) to the valve body, and further wherein at least a portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening (**see figure 1**).

17. **As to claim 29**, Lübeck discloses an apparatus wherein the valve opening is generally planar, and wherein the valve flap curvature biases the valve flap toward the valve opening when the valve flap is attached to the valve body to seal the valve opening (**see figure 1**).

18. **As to claim 30**, Lübeck discloses an apparatus wherein the valve flap curvature biases the valve flap toward the valve opening to seal the valve opening, and wherein the bias of the valve flap toward the valve opening is sufficient to seal between the valve opening in any orientation of the unidirectional valve (**see figure 1**).

19. **As to claim 31**, Lübeck discloses an apparatus wherein the curvature in the valve flap comprises a constant curvature from the first end to the second end (**see last paragraph on page 1**).

20. **As to claim 32**, Lübeck discloses an apparatus wherein the curvature in the valve flap varies from the first end to the second end (**see last paragraph on page 1**).

21. **As to claim 34**, Lübeck discloses an apparatus wherein the unidirectional valve is an exhalation valve (**see page 2 3rd paragraph**).

22. **As to claim 35**, Lübeck discloses an apparatus wherein the unidirectional valve is an inhalation valve (**see page 2 3rd paragraph**).

23. **As to claim 36**, Lübeck discloses an apparatus wherein the valve flap further comprises a top surface and a bottom surface, and at least one support element 2 extending from the top surface of the valve flap (**see figure 1**), wherein the at least one support element provides the curvature shape of the valve flap (**see figures 1 and 2**) that is at least partially flattened when the valve flap seals the valve opening (**see figure 1**).

24. **As to claim 37**, Lübeck discloses an apparatus wherein the valve flap further comprises a top surface and a bottom surface, wherein the valve flap further comprises plurality of support elements **4, 5 and 6** extending from the top surface, wherein each of the plurality of support elements is spaced from each adjacent support elements (**see figure 2**), and wherein the plurality of support elements provide the curvature shape of the valve flap (**see figures 1 and 2**) that is at least partially flattened when the valve flap seals the valve opening (**see figure 1**).

25. **As to claim 38**, Lübeck discloses an apparatus that comprises a facemask (**see page 2 4th paragraph**) comprising an opening formed therethrough; and a unidirectional valve located over the opening in the facemask, the unidirectional valve comprising a valve flap **1** attached to the facemask over the opening (**see figure 1**), the valve flap comprising a curvature from a first end to a second end when the valve flap is not attached to the facemask, wherein the curvature of the valve flap is at least partially flattened when the valve flap seals the opening in the facemask (**see figure 1**).

26. **As to claim 39**, Lübeck discloses an apparatus wherein the at least partially flattened curvature of the valve flap creates a bias that is substantial enough to keep the valve flap sealed over the opening in all orientations (**see figure 1**).

27. **As to claim 40**, Lübeck discloses an apparatus wherein the curvature in the valve flap comprises a constant curvature (**see last paragraph on page 1**).

28. **As to claim 41**, Lübeck discloses an apparatus wherein the curvature in the valve flap varies from the first end to the second end (**see last paragraph on page 1**).

29. As to **claim 42**, Lübeck discloses an apparatus wherein the opening is generally planar and the curvature of the valve flap attached to the facemask over the opening is flattened when the valve flap seals the opening in the facemask (**see figure 1**).

30. As to **claim 44**, Lübeck discloses an apparatus wherein the unidirectional valve is an exhalation valve (**see page 2 3rd paragraph**).

31. As to **claim 45**, Lübeck discloses an apparatus wherein the unidirectional valve is an inhalation valve (**see page 2 3rd paragraph**).

32. As to **claim 46**, Lübeck discloses an apparatus wherein the valve flap further comprises a top surface and a bottom surface, and at least one support element **2** extending from the top surface of the valve flap (**see figure 1**), wherein the at least one support element provides the curvature shape of the valve flap (**see figures 1 and 2**) that is at least partially flattened when the valve flap seals the valve opening (**see figure 1**).

33. As to **claim 47**, Lübeck discloses an apparatus wherein the valve flap further comprises a top surface and a bottom surface, wherein the valve flap further comprises plurality of support elements **4, 5 and 6** extending from the top surface, wherein each of the plurality of support elements is spaced from each adjacent support elements (**see figure 2**), and wherein the plurality of support elements provide the curvature shape of the valve flap (**see figures 1 and 2**) that is at least partially flattened when the valve flap seals the valve opening (**see figure 1**).

34. As to **claims 48 and 49**, Lübeck discloses an apparatus wherein the valve flap comprises a cantilevered valve flap and wherein the first portion of the valve flap is attached to the frame of the valve opening (**see figures 1 and 3**).

35. As to **claim 50**, Lübeck discloses an apparatus wherein the valve flap comprises a cantilevered valve flap, and wherein the first end of the cantilevered valve flap is attached to the facemask (see **figures 1 and 3**).

Claim Rejections - 35 USC § 103

36. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

37. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

38. Claims **16, 33 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lübeck (1213249) in view of Japuntich et al. (US 5,509,436).

39. As to **claims 16, 33 and 43**, Lübeck substantially discloses the claimed invention, see rejection of claims 15, 28 and 38 above, but does not disclose a facemask that is formed of a filtering material. Japuntich discloses an apparatus that does provide a facemask that is formed of a filtering material (see **column 5 lines 10-15**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lübeck's invention

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by providing a facemask that is formed of a filtering material as taught by Japuntich in order to filter large particles.

Double Patenting

40. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

41. Claims **15-18, 28, 38 and 48-50** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **13-16 and 26** of U.S. Patent No.

6,883,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 15, 28 and 38 of the current application and claims 13 and 26 of the patent ‘518 lies in the fact that the patent claims 13 and 26 includes many more elements and is thus much more specific. Thus the invention of claims 13 and 26 is in effect a “species” of the “generic” invention of claims 15, 28 and 38 of the current application. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 29 USPQ2d 2010 (fed. Cir. 1993). Since claims 15, 28 and 38 of the current application is

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anticipated by claims 13 and 26 of patent '518, it is not patentably distinct from claims 13 and 26 of patent '518. **Claim 16 of the current application**, the limitations can be found in claim 14 of patent '518. **Claim 17 of the current application**, the limitations can be found in claim 15 of patent '518. **Claim 18 of the current application**, the limitations can be found in claim 16 of patent '518. **Claim 48 of the current application**, the limitations can be found in claim 26 of patent '518. **Claim 49 of the current application**, the limitations can be found in claim 26 of patent '518. **Claim 50 of the current application**, the limitations can be found in claim 26 of patent '518.

42. Claims 15, 17-20 and 23-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-10, 12 and 18 of U.S. Patent No. 6,883,518 in view of Braun (US 4,934,362). As to **claim 15 of the current application**, claim 1 of patent '518 discloses all the limitations of claim 15 of the current application with the exception of providing a face mask having at least one opening for receiving a unidirectional valve. Braun discloses a unidirectional fluid valve that does provide a face mask having at least one opening for receiving a unidirectional valve, using unidirectional valve on a face mask is well known in the art as taught by Braun. Therefore it would have been obvious to use the face mask of Braun on the unidirectional valve of patent '518 or vice versa. **Claim 17 of the current application**, the limitations can be found in claim 10 of patent '518. **Claim 18 of the current application**, the limitations can be found in claim 8 of patent '518. **Claim 19 of the current application**, the limitations can be found in claim 4 of patent '518. **Claim 26 of the current application**, the limitations can be found in claim 9 of patent '518. **Claim 27 of the current application**, the limitations can be found in claim 12 of patent '518. **Claim 24 of the current**

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application, the limitations can be found in claim 6 of patent '518. **Claim 23 of the current application**, the limitations can be found in claim 5 of patent '518. **Claim 20 of the current application**, the limitations can be found in claim 2 of patent '518. **Claim 25 of the current application**, the limitations can be found in claim 7 of patent '518.

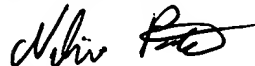
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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